

### Remarks

In the Office Action of May 17, 2004, claims 1-6, 9-15, and 18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lorenzen et al. (U.S. Patent No. 5,730,123) in view of Webb et al. (U.S. Patent No. 4,676,241) and Linder (U.S. Patent No. 4,774,940).

Claims 1-18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Palmer (U.S. Patent No. 6,494,203) in view of Lorenzen and further in view of Webb and Linder.

Claims 7 and 16 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lorenzen in view of Webb and Linder and further in view of Palmer.

Applicants respectfully traverse the §103(a) rejection to claim 1 over Lorenzen in view of Webb and Linder. Respectfully, it would not have been obvious for one of ordinary skill in the art to modify Lorenzen so that the resulting apparatus includes a connector with a body having a passage in which the only access to the passage is through the openings of the first and second ends of the body as set forth in claim 1 of Applicants' application. In order to establish a *prima facie* case of obviousness, there must be some suggestion or motivation either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to combine the reference teachings. There is no suggestion or motivation present for one of ordinary skill in the art to modify Lorenzen upon viewing Webb and Linder such that Lorenzen is modified in order to include a passage in which the only access to the passage is through openings in the first and second ends of the body in fact, there is a suggestion or teaching against doing so as the purpose of Lorenzen would be frustrated by doing so.

Lorenzen discloses and teaches towards a closed ventilating system that is completely different than the connector set forth in claim 1 of Applicants' application. The entire point of Lorenzen is to provide for an apparatus that accommodates multiple access to the respiratory system by providing one or more additional access sites at the proximal adaptor port (see the Abstract of Lorenzen). The adaptor includes a single access port 32 and a plurality of proximal access ports 34, 36, 38, 40, and 42 that allow multiple access to the respiratory circuit (see Lorenzen at column 5, lines 19-21). Access port 36 allows for irrigation or lavage solution to be administered while access port 38 allows for insertion of an aspirating catheter (see Lorenzen at column 5, lines 24-31). Access port 40 allows for the introduction of lavage or medication and access port 42 allows for attachment with an oxygenation catheter assembly (see Lorenzen at column 5, lines 30-39).

Lorenzen is specifically directed towards providing multiple access to the respiratory circuit. Multiple access cannot be obtained if the only access to the distal access port 32 is through the proximal access port 109 (see Figure 1 of Lorenzen). In order to obtain multiple access to the passageway in the tube adaptor 44 of Lorenzen, one or more additional proximal access ports 36, 38, 40 or 42 must be provided in addition to the proximal access port 34 that allows for continual cyclic patient ventilation (see Lorenzen at column 5, lines 20-24). Lorenzen explicitly teaches multiple access to the passageway between the distal and proximal access ports 32, 34. In fact the title of Lorenzen is "Medical Multiple Access Low Dead Space Anti-Microbial Aspirating/Ventilating Closed System Improvements and Methods."

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion,

or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Here, there is simply no teaching, suggestion, or motivation found in Lorenzen to modify this reference so that the only access to the passageway defined by the distal and proximal access ports 32, 34 is through only the openings of these two ports. Lorenzen specifically teaches the desirability of having a plurality of proximal access ports that allow for multiple points of access to the passageway defined by the ports 34, 36 in order to provide for an improved apparatus that allows one to aspirate the lungs, oxygenate the lungs, visually inspect the respiratory system, sample gasses, monitor flow rates, irrigate the respiratory tract and/or administer medication (see the Abstract of Lorenzen and Lorenzen at column 5, lines 18-39).

It would not have been obvious for one skilled in the art to incorporate the devices of Linder or Webb into Lorenzen in order to modify Lorenzen to achieve claim 1 of Applicants' application. If a modification would render the prior art invention being modified unsatisfactorily for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In this instance, modifying Lorenzen so that the passageway defined by the distal and proximal access ports 32, 34 could be accessed only through the access ports 32, 34 would render Lorenzen unsatisfactory for its intended purpose. Upon so doing, it would not be possible for one to obtain any additional access into the passageway defined by the distal and proximal access ports 32, 34. The resulting apparatus would not be able to allow for multiple access and, as such, the resulting device would be rendered unable to work for its intended purpose. The exact modification proposed in the Office Action of May 17, 2004 goes completely against the specific teachings of Lorenzen and would in fact render Lorenzen incapable

of performing in order to achieve the explicitly stated goals of the reference and as such it would not have been obvious for one skilled in the art to modify Lorenzen in such a manner as suggested.

Lorenzen does not suggest the desirability of modifying the apparatus so that access to the passageway defined by the ports 32, 34 is obtained only through the ports 32, 34. In fact, Lorenzen actually teaches to one of ordinary skill in the art **not** to provide access solely through the ports 32, 34, but instead include at least one additional port 36, 38, 40 or 42 through which access may be obtained in order to provide for an apparatus with multiple functionality. As such, Lorenzen explicitly teaches away from the exact modification proposed in the Office Action of May 17, 2004. Therefore, Applicants respectfully submit that there is no motivation present for one of ordinary skill in the art to modify Lorenzen in view of Webb and Linder to obtain the connector as set forth in claim 1 of Applicants' application.

As stated, claim 1 of Applicants' application was also rejected in the Office Action under 35 U.S.C. §103(a) as being unpatentable over Palmer in view of Lorenzen and further in view of Webb and Linder. Applicants respectfully traverse the §103(a) rejection to claim 1 over Palmer in view of Lorenzen and in view of Webb and Linder. As stated in the Office Action of May 17, 2004, Palmer does not disclose a structure in which the only access to the passage is through the openings of the first and second ends as set forth in claim 1 (see page 5, paragraph of the Office Action of May 17, 2004). Further, Palmer actually teaches away from such a structure.

Palmer discloses an adapter 44 that has a passageway 84 and a passageway 86 in communication with one another and are accessed by access ports 32 and 36. As

with the structure in Lorenzen, the adapter 44 in Palmer also includes an additional access port 34 that provides access to the passageways 84, 86.

The purpose of access port 34 is to provide for selective insertion and subsequent removal of an aspirating catheter assembly, replacement of residual carbon dioxide with oxygen, temperature measurement, monitoring instruments, to obtain samples of gasses, and/or to allow insertion of visual inspection instruments (see Palmer at column 3, lines 50-58). It is therefore the case that the adapter 44 of Palmer also provides for multiple access to the passageways 84, 86 defined in the access ports 32, 36. In fact, Palmer is specifically directed towards an apparatus in which the “dominant object” of the design is to provide a closed ventilating system that is capable of accommodating multiple access to the respiratory system of a patient (see Palmer at column 2, lines 28-31). Palmer states that a need exists in finding a way to provide multiple treatments to a patient that may also be performed at the same time (see Palmer at column 1, lines 26-28). Palmer explicitly teaches toward meeting this need in the art by providing for an apparatus that accommodates multiple access to the respiratory system (see Palmer at column 1, line 66 to column 2, line 4). As with Lorenzen, Palmer specifically teaches towards an adapter that provides multiple access to the passageway. Incorporating Lorenzen into Palmer would produce a resulting design that also includes multiple access to the passageway because both Palmer and Lorenzen are each directed towards designs that are specifically directed towards providing multiple accesses to the passageway.

It would not have been obvious for one skilled in the art to modify the design of Palmer or the resulting design achieved through the combination of Palmer and Lorenzen by incorporating Webb and Linder in the manner set forth in page 5,

paragraph 4 of the Office Action of May 17, 2004. In order to establish a case of *prima facie* obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. In the instant case, there is no suggestion or motivation present for one of ordinary skill in the art to modify either Palmer or the combination of Palmer and Lorenzen so that the passageway is accessed only through the openings in the first and second ends. The references specifically teach toward designs in which multiple access is provided, and state that these types of designs are desirable over previous systems.

Modification of the adapter 44 in Palmer or the adapter resulting from the combination between Palmer and Lorenzen in further view of Webb and Linder would render this reference or combination of references unsatisfactory for its intended purpose because any such modification would remove the multiple access feature. If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there can be no suggestion or motivation to make the proposed modification. In our case, removing the multiple access feature of Palmer or the combination of Palmer and Lorenzen would make the resulting design unsatisfactory because it would not allow for one to access the respiratory tract in the prescribed manner in order to provide suctioning, temperature readings, oxygenation, visual inspection, administration of medication, etc. It would not have been obvious for one skilled in the art to combine Palmer in view of Lorenzen and further in view of Webb and Linder because doing so would produce an adapter that would not work for its intended purpose.

Further, Palmer explicitly teaches having the access port 34 be aligned with the passageway 84 in order to accommodate ease of insertion of the slideable aspirating catheter tube 120 (see Palmer at column 5, lines 37-43). Modifying Palmer so that access to the passageways 84, 86 may only be obtained through openings in the access port 32 and 36 would therefore go completely against this teaching and the reference because, as set forth in claim 1 of the present application, the passageways would be placed at approximately 120 degree angle. As such, Palmer further teaches away from the modification suggested in the Office Action of May 17, 2004.

Palmer and Linder, both individually and in combination, do not suggest or teach modification in which multiple access is eliminated. In fact, the references are specifically directed towards structures that provide for multiple access so that various benefits and advantages can be realized. As such, the references specifically teach away from the modifications set forth in the Office Action of May 17, 2004 and a case of *prima facie* obviousness is not present.

Therefore, Applicants respectfully submit that claim 1 of the present application defines over the combination of Lorenzen in view of Webb and Linder and the combination of Palmer in view of Lorenzen and further in view of Webb and Linder and is believed to be in condition for allowance. Also, all claims that depend from claim 1 (claims 2-8) are also believed to be in condition for allowance. The rejections to claims 2-8 are moot due to the allowance of claim 1.

Claim 9 also calls for a connector in which the only access to the first and second passages is through the openings in the first and second ends, and claim 18 calls for a connector in which the only access to the passageway is through openings in the first and second ends. Although not exact, the structure set forth in claims 9 and 18 is

similar to that called for in claim 1 and Applicants respectfully submit that claims 9 and 18 define over the combination of Lorenzen in view of Webb and Linder and also over the combination of Palmer in view of Lorenzen and further in view of Webb and Linder for essentially the same reasons as discussed above with respect to claim 1 and are believed to be in condition for allowance. Also, all claims that depend from claim 9 (claims 11-17) are also believed to be in condition for allowance. The rejections to claims 11-17 are moot due to the allowance of claim 9.

With the present Amendment, Applicants submit that all pending claims are allowable and that the application is in condition for allowance. Favorable action thereon is respectfully requested. The Examiner is encouraged to contact the undersigned at his convenience to resolve any remaining issues.

Respectfully submitted,

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